Draft Guidance for Industry and FDA Staff

Class II Special Controls Guidance Document: Tinnitus Masker Devices

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Ear Nose and Throat Devices Branch
Division of Ophthalmology and Ear Nose and Throat Devices
Office of Device Evaluation

Preface

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This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

1. Introduction

This guidance document describes a means by which tinnitus masker devices (TMDs) intended for use in audiological/otological treatment of symptomatic tinnitus may comply with the requirement of Class II Special Controls. This guidance will be issued in conjunction with a Federal Register notice announcing the proposal to establish the Class II (special controls) classification of this device type. This guidance is issued for comment purposes only. If a final rule for this device is not issued, this guidance will not be issued as a special control.

Following the effective date of a final rule for the device, any firm submitting a 510(k) for tinnitus masker devices will need to address the issues covered in this special controls guidance. However, the firm need only show that its device meets the recommendations of this guidance or, in some other way, provides equivalent assurances of safety and effectiveness.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word "should" in Agency guidances means that something is suggested or recommended, but not required.

The Least Burdensome Approach

This draft guidance document reflects our careful review of what we believe are the relevant issues related to TMDs and what we believe would be the least burdensome way of addressing these issues. If you have comments on whether there is a less burdensome approach, however, please submit your comments as indicated on the cover of this document.

2. Background

FDA believes that special controls, when combined with the general controls, will be sufficient to provide reasonable assurance of the safety and effectiveness of TMDs. Thus, a manufacturer who intends to market a device of this generic type should (1) conform to the general controls of the Federal Food, Drug, and Cosmetic Act (the Act), including the premarket notification requirements described in 21 CFR 807, Subpart E, (2) address the specific risks to health associated with TMDs identified in this guidance, and (3) obtain a substantial equivalence determination from FDA prior to marketing the device.

This special controls guidance document identifies the proposed regulation and product codes for TMDs (refer to **Section 4. Scope**). In addition, other sections of this special controls guidance document list the risks to health identified by FDA and describe measures that, if followed by manufacturers and combined with the general controls, will generally address the risks associated with these devices and lead to a timely 510(k) review and clearance. This document supplements other FDA documents regarding the content requirements of a 510(k) submission. You should also refer to 21 CFR 807.87 and **"How to Prepare a 510(k) Submission"** on FDA Device Advice at http://www.fda.gov/cdrh/devadvice/314.html.

Under **"The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications; Final Guidance,"**[1] a manufacturer may submit a Traditional 510(k) or an Abbreviated 510(k). FDA believes an Abbreviated 510(k) provides the least burdensome means of demonstrating substantial equivalence for a new device, particularly once a class II special controls guidance document has been issued. Additionally, manufacturers considering modifications to their own cleared devices may lessen the regulatory burden by submitting a Special 510(k).

3. The Content and Format of an Abbreviated 510(k) Submission

An Abbreviated 510(k) submission must include the required elements identified in 21 CFR 807.87, including the proposed labeling for the device sufficient to describe the device, its intended use, and the directions for its use. In an Abbreviated 510(k), FDA

[1] http://www.fda.gov/cdrh/ode/parad510.html

may consider the contents of a summary report to be appropriate supporting data within the meaning of 21 CFR 807.87(f) or (g); therefore, we recommend that you include a summary report. The report should describe how this special controls guidance document was used during the device development and testing and should briefly describe the methods or tests used and a summary of the test data or description of the acceptance criteria applied to address the risks identified in this document, as well as any additional risks specific to your device. This section suggests information to fulfill some of the requirements of section 807.87 as well as some other items that we recommend you include in an Abbreviated 510(k).

Coversheet

The coversheet should prominently identify the submission as an Abbreviated 510(k) and cite the title of this special controls guidance document.

Proposed Labeling

Proposed labeling should be sufficient to describe the device, its intended use, and the directions for its use. (Refer to **Section 9. Labeling** for specific information that should be included in the labeling for devices of the types covered by this guidance document.)

Summary Report

We recommend that the summary report contain a:

Description of the device and its intended use

We recommend that the description include a complete discussion of the performance specifications and, when appropriate, detailed, labeled drawings of the device. (Refer to **Section 5. Device Description** for specific information that we recommend you include in the device description for devices of the type covered by this guidance document.) You should also submit an "indications for use" enclosure.[2]

Description of device design

We recommend that you include a brief description of the device design requirements.

Identification of the risk analysis method

We recommend that you identify the risk analysis method(s) used to assess the risk profile in general as well as the specific device's design and the results of this analysis. (Refer to **Section 6. Risks to Health** for the risks to health generally associated with the use of this device that FDA has identified.)

[2] Refer to http://www.fda.gov/cdrh/ode/indicate.html for the recommended format.

Discussion of the device characteristics

We recommend that you discuss the device characteristics that address the risks identified in this class II special controls guidance document, as well as any additional risks identified in your risk analysis.

Description of performance aspects

We recommend that you include a brief description of the test method(s) you have used or intend to use to address each performance aspect identified in **Sections 7-10** of this special controls guidance document. If you follow a suggested test method, you may cite the method rather than describing it. If you modify a suggested test method, you may cite the method but should provide sufficient information to explain the nature of and reason for the modification. For each test, you may either (1) briefly present the data resulting from the test in clear and concise form, such as a table, **or** (2) describe the acceptance criteria that you will apply to your test results.[3] (See also 21 CFR 820.30, Subpart C - Design Controls under the Quality System Regulation.)

Reliance on Standards

If you choose to rely on a recognized standard for any part of the device design or testing, you may include either a:

- statement that testing will be conducted and meet specified acceptance criteria before the product is marketed; or
- declaration of conformity to the standard.[4]

Because a declaration of conformity is based on results from testing, we believe you cannot properly submit a declaration of conformity until you have completed the testing the standard describes. For more information, please refer to section 514(c)(1)(B) of the Act and the FDA guidance, **Use of Standards in Substantial Equivalence Determinations**.[5]

If it is not clear how you have addressed the risks identified by FDA or additional risks identified through your risk analysis, we may request additional information about aspects of the device's performance characteristics. We may also request additional

[3] If FDA makes a substantial equivalence determination based on acceptance criteria, the subject device should be tested and shown to meet these acceptance criteria before being introduced into interstate commerce. If the finished device does not meet the acceptance criteria and, thus, differs from the device described in the cleared 510(k), FDA recommends that submitters apply the same criteria used to assess modifications to legally marketed devices (21 CFR 807.81(a)(3)) to determine whether marketing of the finished device requires clearance of a new 510(k).

[4] See **Required Elements for a Declaration of Conformity to a Recognized Standard** (Screening Checklist for All Premarket Notification [510(K)] Submissions), http://www.fda.gov/cdrh/ode/reqrecstand.html.

[5] http://www.fda.gov/cdrh/ode/guidance/1131.html

information if we need it to assess the adequacy of your acceptance criteria. (Under 21 CFR 807.87(l), we may request any additional information that is necessary to reach a determination regarding substantial equivalence.)

As an alternative to submitting an Abbreviated 510(k), you can submit a Traditional 510(k) that provides all of the information and data required under 21 CFR 807.87 and described in this guidance. A Traditional 510(k) should include all of your methods, data, acceptance criteria, and conclusions. Manufacturers considering modifications to their own cleared devices should consider submitting Special 510(k)s.

The general discussion above applies to any device subject to a special controls guidance document. The following is a specific discussion of how you should apply this special controls guidance document to 510(k) submissions for TMDs.

4. Scope

The scope of this document is limited to TMDs as described in 21 CFR 874.3400, class II, product code KLW.

Sec. 874.3400 Tinnitus masker

A tinnitus masker is an electronic device intended to generate noise of sufficient intensity and bandwidth to mask ringing in the ears or internal head noises. Because the device is able to mask internal noises, it is also used an aid in hearing external noises and speech.

TMDs include “in-the-ear” and “behind-the-ear” air conduction configurations. The device type also includes ultrasound TMDs.

5. Device Description

We recommend that you identify your device by regulation number and product code identified in **Section 4. Scope** and include the following information:

- a description of the components of the device and its assembly
- a description of any accessories used with the device
- the range of dimensions, shapes, and device designs
- engineering drawings, if applicable
- a description of the principle of operation (i.e., the scientific principles behind how the device achieves its intended use).

For ultrasound TMDs, engineering drawings should show:

- detailed dimensions of the circular tip area of the transducer that will contact the mastoid area
- associated static force necessary to achieve output levels
- how the static force is achieved.

We recommend that you compare your device with the predicate device to show how the new device is both similar to and different from the legally marketed device. Side by side comparisons, put in tabular format, are desirable. We also recommend that you describe how any differences may affect the comparative safety and performance of the new device.

We recommend that you provide the manufacturer and name of the predicate device, with its 510(k) number, if available.

6. Risks to Health

In the table below, FDA has identified the risks to health generally associated with the use of TMDs addressed in this document. The measures recommended to mitigate these identified risks are given in this guidance document, as shown in the table below. You should also conduct a risk analysis to identify any other risks specific to your device and submit the results of this analysis. If you elect to use an alternative approach to address a particular risk identified in this document, or have identified risks additional to those in this document, you should provide sufficient detail to support the approach you have used to address that risk.

Identified Risks	Recommended Mitigation Measures
Side effects, including worsening tinnitus	Section 8. Clinical Testing Section 9. Labeling
Change in hearing	Section 7. Preclinical Testing Section 8. Clinical Testing Section 9. Labeling
Adverse Tissue Reaction	Section 7. Preclinical Testing
Electrical Hazards	Section 7. Preclinical Testing
Tissue Heating or Cavitation (ultrasound TMDs only)	Section 7. Preclinical Testing
Improper Use	Section 9. Labeling

7. Preclinical Testing

FDA recommends preclinical testing if the device's method of action is different from or in addition to masking, e.g., tinnitus suppression or cancellation. Bench testing should assess any differences in the performance of the device that may result from the new method of action.

TMDs include parts that contact patients. FDA recommends that you evaluate the biocompatibility of the patient-contacting materials in your device. Please refer to the guidance documents entitled Blue Book Memo, G95-1, **Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and**

Testing," http://www.fda.gov/cdrh/g951.html. You should select biocompatibility tests for limited duration of contact with intact skin, as appropriate for your device design and submit the pass/fail criteria you used in testing. If identical materials are used in a predicate device with the same type and duration of patient contact, you may identify the predicate device in lieu of performing biocompatibility testing.

If your device design includes patient contact with any electrically powered device component, FDA recommends that the device meet the electrical safety requirements of IEC 60601 1 (1988): Medical electrical equipment - Part 1: General requirements for safety, including Amendment 1 (1991) and Amendment 2 (1995). We recommend that you evaluate your device as described and document the results in your design history file as a part of the Quality Systems Requirements (21 CFR 820.20).[6]

For ultrasound TMDs, we recommend that you conduct a detailed analysis of potential adverse effects related to the ultrasound energy, such as thermal heating of tissue and blood; extra auditory effects; and changes in auditory threshold. We also recommend that you submit documentation that the output intensity does not reach levels that alter the biological thermal mechanism or cavitation mechanism.[7]

8. Clinical Studies

In accordance with the least burdensome provisions of the Act, the Agency will rely upon well-designed bench testing rather than recommending clinical studies for new devices unless there is a specific justification for asking for clinical information to support a determination of substantial equivalence. While, in general, clinical studies will not be needed for most TMDs, FDA may recommend that you collect clinical data for a TMD for any of the following:

- design, i.e., masking pattern, peak intensity or duration, etc. dissimilar from any design previously cleared under a premarket notification
- new technology, i.e., technology different from that used in legally marketed TMDs
- indications for use dissimilar from TMDs of the same type.

FDA will always consider alternatives to clinical testing when the proposed alternatives are supported by an adequate scientific rationale.

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[6] If your device is labeled sterile, we recommend that you follow the guidance for devices intended for contact with intact skin in **Updated 510(k) Sterility Review Guidance K90-1; Final Guidance for Industry and FDA**, http://www.fda.gov/cdrh/ode/guidance/361.html.

[7] Product and supplemental reporting requirements are currently applicable according to 21 CFR 1002 Table 1 (in addition to submitting the 510(k)). The reporting guide is available online at http://www.fda.gov/cdrh/radhlth/pdf/usmrpt0p.pdf.

If you conduct a clinical study, we recommend that your study address issues related to changes in auditory thresholds, pre- and post-exposure to ultrasonic masking stimuli, possible negative side effects of fatigue, headaches, nausea, irritability, and "fullness" in the ear.

If a clinical study is needed to demonstrate substantial equivalence, i.e., conducted prior to obtaining 510(k) clearance of the device, the study must be conducted under the Investigational Device Exemptions (IDE) regulation, 21 CFR Part 812. Generally, FDA believes that TMD devices addressed by this guidance document are non-significant risk devices and, therefore, the study is subject to the abbreviated requirements of 21 CFR 812.2(b).[8] In addition to the requirements of section 21 CFR 812.2(b), sponsors of such trials must comply with the regulations governing institutional review boards (21 CFR Part 56) and informed consent (21 CFR Part 50).

After FDA determines that the device is substantially equivalent, clinical studies conducted in accordance with the indications cleared in the 510(k), including clinical design validation studies conducted in accordance with the quality systems regulation, are exempt from the investigational device exemptions (IDE) requirements. However, such studies must be performed in conformance with 21 CFR Part 56 and 21 CFR Part 50.

9. Labeling

Your 510(k) submission should include labeling in sufficient detail to satisfy the requirements of 21 CFR 807.87(e). The following suggestions are aimed at assisting you in preparing labeling that satisfies the requirements of 21 CFR Part 801.[9]

Professional Labeling

We recommend the intended use identify the intended patient population. We also recommend that the intended use be based on the particular characteristics of your TMD, related to its material, design, performance characteristics, and describes whether the device is for masking only.

We recommend that the labeling warn against use when preexisting conditions are present, such as:

- visible congenital or traumatic deformity of the ear
- history of active drainage from the ear within the previous 90 days
- history of sudden or rapidly progressive hearing loss within the previous 90 days
- acute or chronic dizziness

[8] See http://www.fda.gov/oc/ohrt/irbs/devices.html#risk.

[9] Although final labeling is not required for 510(k) clearance, final labeling must comply with the requirements of 21 CFR Part 801 before a device is introduced into interstate commerce. In addition, final labeling for prescription devices must comply with 21 CFR 801.109. Labeling recommendations in this guidance are consistent with the requirements of Part 801.

- unilateral hearing loss of sudden or recent onset within the previous 90 days.

Patients/users experiencing any of these conditions should seek medical evaluation.

Patient Labeling[10]

We recommend that you provide patient labeling or user instructions that discuss:

- hearing health care professional diagnosis, fitting, and followup care
- risks
- benefits
- specifications.

We also recommend that user instructions include information about frequency and duration of use and any precautions regarding intensity or loudness.

We also recommend that any patient labeling or user instructions warn users to discontinue use and seek medical evaluation if any of the following conditions occur:

- chronic skin irritation on, near, or around the site of device placement
- unusual side effects (e.g., dizziness, nausea, headaches, heart palpitations)
- perceived decrease in auditory function (e.g., decreased loudness, speech not as clear).

[10] For general guidance on patient labeling, see **Guidance on Medical Device Patient Labeling**, http://www.fda.gov/cdrh/ohip/guidance/1128.html.